Study of Efficacy and Safety of LEE011 in Men and Postmenopausal Women With Advanced Breast Cancer (MONALEESA 3)

13/08/2025 19:29:30

Main Information

Primary registry identifying number
LBCTR2019080232

Protocol number
CLEE011F2301

MOH registration number
6427/ص

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
LCTR was recently initiated, original file was previously submitted by Paper

Date of registration in national regulatory agency
15/07/2015

Primary sponsor
Novartis Pharma Services Inc.

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
06/07/2020

Date of registration in national regulatory agency
15/07/2015

Public title
Study of Efficacy and Safety of LEE011 in Men and Postmenopausal Women With Advanced Breast Cancer (MONALEESA 3)

Acronym

Scientific title
A Randomized Double-blind, Placebo-controlled Study of Ribociclib in Combination With Fulvestrant for the Treatment of Men and Postmenopausal Women With Hormone Receptor Positive, HER2-negative, Advanced Breast Cancer Who Have Received no or Only One Line of Prior Endocrine Treatment

Acronym

Brief summary of the study: English
This is a multi-center, randomized double-blind, placebo controlled study of ribociclib in combination with fulvestrant for the treatment of postmenopausal women and men with hormone receptor positiv e, Her2 negative, advanced breast cancer who have received no or only one line of endocrine therapy for advanced breast cancer.

Brief summary of the study: Arabic
دراسة عشوائية مزدوجة التعمية ومرتكزة على المقارنة بدواء وهمي حول دواء ريبوسيكليب بالتزامن مع فولفيسترانت لعلاج الرجال والنساء بعد الذين لم يتلقوا أي علاج سابق للغدد الصمّاء أو تلقوا2انقطاع الطمث المصابين بسرطان الثدي المتقدّم الإيجابيّ مستقبلات الهرمون وسلبيّ الهير نوعاً واحداً منه فقط

Health conditions/problem studied: Specify
advanced breast cancer

Interventions: Specify
•Drug: Ribociclib

Riblociclib 600mg daily oral (days 1 to 21 in a 28-day Cycle)

Other Name: LEE011

•Drug: fulvestrant
Fulvestrant 500mg i.m. injections every 28 days (Cycle n Day 1) with 1 additional dose on Day 15 of Cycle 1

Other Name: Faslodex

•Drug: Ribociclib placebo
Riblociclib placebo 600mg daily oral (days 1 to 21 in a 28-day Cycle)

Other Name: LEE011 placebo

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:
1.Patient is an adult male/female ≥ 18 years old at the time of informed consent and has signed informed consent before any trial related activities and according to local guidelines. Female patients must be postmenopausal.
2.Patient has a histologically and/or cytologically confirmed diagnosis of estrogen-receptor positive and/or progesterone receptor positive breast cancer by local laboratory and has HER2-negative breast cancer.
3.Patient must have either measurable disease by RECIST 1.1 or at least one predominantly lytic bone lesion.

4.Patient has advanced (loco regionally recurrent not amenable to curative therapy, e.g. surgery and/or radiotherapy, or metastatic) breast cancer.

Patients may be:
◦newly diagnosed advanced/metastatic breast cancer, treatment naïve
◦relapsed with documented evidence of relapse more than 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for advanced/metastatic disease
◦relapsed with documented evidence of relapse on or within 12 months from completion of (neo)adjuvant endocrine therapy with no treatment for advanced/metastatic disease
◦relapsed with documented evidence of relapse more than 12 months from completion of adjuvant endocrine therapy and then subsequently progressed with documented evidence of progression after one line of endocrine therapy (with either an antiestrogen or an aromatase inhibitor) for advanced/metastatic disease
◦newly diagnosed advanced/metastatic breast cancer at diagnosis that progressed with documented evidence of progression after one line of endocrine therapy (with either an antiestrogen or an aromatase inhibitor)

5.Patient has an Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1
6.Patient has adequate bone marrow and organ function

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:
1.Patient with symptomatic visceral disease or any disease burden that makes the patient ineligible for endocrine therapy per the investigator's best judgment.
2.Patient has received prior treatment with chemotherapy (except for neoadjuvant/ adjuvant chemotherapy), fulvestrant or any CDK4/6 inhibitor.
3.Patient with inflammatory breast cancer at screening .
4.Patient with CNS involvement unless they are at least 4 weeks from prior therapy completion to starting the study treatment and have stable CNS tumor at the time of screening and not receiving steroids and/or enzyme inducing anti-epileptic medications for brain metastases
5.Clinically significant, uncontrolled heart disease and/or cardiac repolarization abnormality

6.Patient is currently receiving any of the following substances and cannot be discontinued 7 days prior to start the treatment:
◦Known strong inducers or inhibitors of CYP3A4/5,
◦That have a known risk to prolong the QT interval or induce Torsades de Pointes.
◦Those have a narrow therapeutic window and are predominantly metabolized through CYP3A4/5.
◦Herbal preparations/medications, dietary supplements.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope
Therapy

Trial scope: Specify scope
N/A

Study design: Allocation
Randomized controlled trial

Study design: Masking
Blinded (masking used)

Study design: Control
Placebo

Study phase
3

Study design: Purpose
Treatment

Study design: Specify purpose
N/A

Study design: Assignment
Parallel

Study design: Specify assignment
N/A

IMP has market authorization
Yes, Lebanon and Worldwide

IMP has market authorization: Specify
Worldwide ; Lebanon MOH approval: Postmenopausal

Name of IMP
Ribociclib (Kisqali)

Year of authorization
2017

Month of authorization
8

Type of IMP
Others

Pharmaceutical class
Orally bioavailable, highly selective small molecule inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6).

Therapeutic indication
Men and Pre/Postmenopausal Women With Hormone Receptor-positive (HR+) HER2-negative (HER2 -) Advanced Breast Cancer

Therapeutic benefit
increase OS & PFS

Study model
N/A

Study model: Explain model
N/A

Study model: Specify model
N/A

Time perspective
N/A

Time perspective: Explain time perspective
N/A

Time perspective: Specify perspective
N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

Biospecimen description

Samples with DNA**	Q2 lab is the lab used in this study, ambiant lab samples shipped to central lab, Blood and urine samples . Samples for circulating tumor DNA (ctDNA) is also required

Target sample size
6

Actual enrollment target size
6

Date of first enrollment: Type
Actual

Date of first enrollment: Date
22/12/2015

Date of study closure: Type
Actual

Date of study closure: Date
23/02/2021

Recruitment status
Complete

Recruitment status: Specify

Date of completion
06/05/2016

IPD sharing statement plan
No

IPD sharing statement description
Undecided ; Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.
This trial data is currently available according to the process described on www.clinicalstudydatarequest.com.

Additional data URL
https://clinicaltrials.gov/ct2/show/record/NCT02422615?term=breast+cancer+lebanon&draw=10

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT02422615

Sources of Monetary or Material Support

Name
Novartis Pharma Services Inc.

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Nagi El Saghir	Beirut	Lebanon	961 1 350000 ext 7489	ns23@aub.edu.lb	American University of Beirut Medical Center
Scientific	Hind Khairallah	Sin El Fil	Lebanon	+961 1 512002 Ext. 271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.
Public	Marwan Ghosn	Beirut	Lebanon	00961 1 613395	marwanghosnmd@yahoo.com	Hotel Dieu De France

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Hotel Dieu De France	Marwan Ghosn	Hematology Oncology	Approved
American University of Beirut Medical Center	Nagi El Saghir	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	14/09/2015	Fuad Ziyadeh	fz05@aub.edu.lb	+961 (0) 1 350 000 ext:5445
Hotel Dieu de France	17/06/2015	Nancy Alam	nancy.alam@usj.edu.lb	+961 (0) 1 421000 ext 2335

Countries of Recruitment

Name
Lebanon
Argentina
Austria
Belgium
Bulgaria
Canada
Colombia
Czech Republic
France
Denmark
Germany
Hungary
Italy
Jordan
Mexico
Switzerland
United Kingdom
United States of America

Health Conditions or Problems Studied

Condition	Code	Keyword
Advanced Breast Cancer	Breast, unspecified (C50.9)	Advanced Breast Cancer

Interventions

Intervention	Description	Keyword
ICF, medical history, demography, radiology, vital signs, IMP administration	ICF, medical history, demography, radiology, vital signs, IMP administration	ICF, Lab, IMP, radiology

Primary Outcomes

Name	Time Points	Measure
Progression Free Survival (PFS) Per Investigator Assessment	26 months	26 months

Key Secondary Outcomes

Name	Time Points	Measure
Overall Survival (OS)	58 months	58 months
•Progression Free Survival (PFS) Per Blinded Independant Review Committee (BICR)	26 months	26 months
•Overall Response Rate (ORR)	26 months	26 months
•Safety and Tolerability of LEE011	26 months	26 months

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files